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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/005,902 | 12/04/2001 | Dale Brown | 5369/00015 | 7185 |
| 22910 7590 03/18/2009 BANNER & WITCOFF, LTD. 28 STATE STREET 28th FLOOR BOSTON, MA 02109-9601 | | | | |
| EXAMINER | | | | |
| GEMBEHL, SHURLEY V | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1618 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 03/18/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/005,902

Applicant(s)

BROWN ET AL.

Examiner

SHIRLEY V. GEMBEH

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1448 or PTO-889)
Paper No(s)/Mail Date 10/16/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/5/08 has been entered.
2. Applicant's arguments filed 12/5/08 have been fully considered but they are not deemed to be persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 15-25 are pending in this office action.
5. The information disclosure statement (IDS) submitted on 10/16/08 is acknowledged and has been reviewed.

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6. Claims 15-25 rejected under 35 U.S.C. 103(a) as being unpatentable over Keller, (US 5,129,824 (824)) in view of Hill, (US 5,993,784 (784)) and Hill et al., (US 5,057,309 (309)) in view of Kim et al., (US, 6,045,800 (800)) is withdrawn due to the amendment to the claims. Applicant's arguments with respect to claims 15-25 have been considered but are moot in view of the new ground(s) of rejection below.

7. Claims 15-25 rejected under 35 U.S.C. 103(a) as being unpatentable over Keller, (US 5,129,824) in view of Hill, (US 5,993,784) and Aberg et al., (US 5,807,541) as evidenced by Miller (US 5,123,841).

Keller teaches a self-treatment method of treating gingival comprising: physically removing biofilm from the tooth surface (i.e., supra gingivally) with a tooth brush (see abstract, as required by item 15a), which also reasonably removes biofilm from the interproximal tooth surface (between the teeth) (as required by item 15b). Keller also teaches that dental floss is employed to remove biofilm from subgingival surfaces (as required by item 15c). Keller further teaches the addition of medicaments (i.e., therapeutic agents) to the tooth brush and dental floss.

However Keller fails to teach using ribbed and grooved bristled tooth brushes with a tooth paste containing soft abrasives, or use of therapeutic agents such as NSAIDs (i.e., as it relates to claims 23-25).

Hill teaches low foaming toothpaste with soft abrasives that is employed with a ribbed and grooved bristled tooth brush (as required by instant claim 15 a), wherein the toothbrush includes 3-5 ribs and grooves (as it relates to claims 16-18 and 19; see

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abstract, Figs 1-4b and col. 6, lines 47 and 58 for the abrasives) and wherein the abrasives are silica or alumina silica; (same as Applicant's disclosure of a soft abrasive recited). Brushing with tooth paste intrinsically removes biofilm. Hill further teaches the toothpaste comprises non-ionic surfactants and polydimethylsiloxanes, (see col. 7, lines 45-47 and col. 11, line 33, as required by instant claims 20-22). Because toothpaste would be used on a toothbrush, it would be obvious that brushing of the supragingival occurs. It should be noted that with regards to the limitation of "gingival detachment of at least 3 mm", Keller teaches (see Fig.2) inflamed teeth creates pockets, which thus are detached, as evidence by Miller ('841) where he teaches pocket formation is of 3-4 mm (US 5,123,841, col. 4, lines 33-35).

However, Hill fails to teach the specific therapeutic agents such as NSAIDs and dental floss.

Aberg et al teach preventing dental caries by administering toothpaste with a medicament such as NSAIDs for treating periodontal disease, (see abstract and col. 6, lines 49-58; as required by instant claims 23-25). Because toothpaste would be used on a toothbrush, it would be obvious that brushing of the supragingival occurs.

However Aberg fails to teach using ribbed and grooved bristled tooth brushes with a tooth paste containing soft abrasives.

One of ordinary skill in the art would have been motivated to expand the teaching of Keller to remove biofilm removal with a tooth brush and floss by substituting the tooth brush of Keller with Hill's, since Hill specifically teach use of ribbed grooved bristle tooth brushes to brush the supragingival tooth surface of the tooth, wherein it is well known

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that brushing with toothpaste removes biofilm. Employing the toothbrush of Hill and the soft abrasive toothpaste of Hill will intrinsically result in the abrasives physically being worked into the supra and subgingival pockets of the patients mouth suffering from periodontal disease.

It would have been obvious to one of ordinary skill in the art to have combined the teachings of Keller and Hill with Aberg et al and add a NSAID to the toothpaste or dental floss for the treatment of periodontal disease because Aberg teaches periodontal disease relates to a condition in which the gingival and the alveolar bone become detached if periodontal disease is not treated, and the bacteria that causes the periodontal disease can gain access to the blood stream and cause vascular disease. Therefore, one of ordinary skill in the art would have been motivated to add Aberg's NSAID to toothpaste for brushing or add NSAID to dental floss for flossing and remove biofilm in pockets of the tooth of the patient suffering from periodontal disease because Keller teaches that therapeutic agents maybe added to such formulation with a reasonable expectation of success.

8. No claim is allowed.
9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Grady (Grady New York Times 1998)

- diseases of the mouth are linked to heart disease (see entire publication).

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHIRLEY V. GEMBEH whose telephone number is (571)272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL HARTLEY can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/S. V. G./
Examiner, Art Unit 1618
2/17/09

/Robert C. Hayes/
Primary Examiner, Art Unit 1649